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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|----------------------------------|------------------|
| 10/702,306 | 11/06/2003 | Keith Davis | 2070US | 7970 |
| 22881 | 7590 | 08/23/2005 | EXAMINER GEBREYESUS, KAGNEW H | |
| ERIC J. KRON ICORIA, INC. 108 T.W. ALEXANDER DRIVE, BUILDING 1A POST OFFICE BOX 14528 RESEARCH TRIANGLE PARK, NC 27709 | | | ART UNIT 1652 | PAPER NUMBER |

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/702,306

Applicant(s)

DAVIS ET AL.

Examiner

Kagnew H. Gebreyesus

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Priority

Priority is acknowledged for this application which is the national phase under 35 U.S.C. 371 of PCT International 5 Application No. PCT/US02/14694, that has an international filing date of November 14, 2002, which designated the United States of America and which claims the benefit of U.S. Provisional Application Serial No. 60/289,492, filed May 8, 2001.

Claim Objections

1. Claims 1-17 are objected to because of the following informalities: The claims are objected to for the recitation "FHT". This term must be written in full before the first instance of its appearance in abbreviated form. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 3, 5-10, 12-14, 16 and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are directed to the use of a genus of flavanone 3-hydroxylase (FHT) polypeptide molecules from any source in the method of identifying a candidate herbicidal compound. The specification teaches the structure of only a single representative species of such flavanone 3-hydroxylase (FHT) from *Arabidopsis thaliana* comprising SEQ ID NO: 2 and the use of said polypeptide in the method of identifying a compound as a candidate for a herbicide.

Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of a flavanone 3-hydroxylase (FHT) in a method of identifying a compound as a candidate for herbicide. Given this lack of description of representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 1, 2, 3, 5-10, 12-14, 16 and 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for identifying a compound as a candidate for a herbicide using an enzyme of SEQ ID NO: 2 from *Arabidopsis thaliana*, does not reasonably provide enablement for the use of any FHT from any source (claim 1, 8, 17) or an FHT from any plant (claim 2, 6, 7, 9, 12, 13, 16) in the method for identifying a compound as a candidate for a herbicide as encompassed by the claims.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Claims 1, 2, 5-9, 12, 13, 16 and 17 are so broad as to encompass the use of any FHT polypeptide or fragment thereof comprising as little as 10 consecutive amino acids from any plant FHT, an amino acid sequence having at least 85% sequence identity with any plant FHT and having at least 50% activity or an FHT from any plant in the method of identifying a compound as a candidate for a herbicide. Claims 3, 10 and 14 are so broad as to encompass the use of any *Arabidopsis thaliana* FHT in a method of identifying a compound as a candidate herbicide.

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large variety of FHT enzymes to be used in the method

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of identifying a compound as a candidate for a herbicide claimed broadly encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *re Wands* (858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)). The *Wands* factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass any FHT from any source, any FHT with at least 80-85% homology to any FHT from any source, any fragments thereof with at least ten amino acids used in a method of identifying a candidate herbicidal compound. The specification provides guidance and examples for making an *Arabidopsis thaliana* FHT of SEQ ID NO: 2 and method of using said FHT in a method of identifying a candidate herbicidal compound. However, the specification does not teach the specific structure of any FHT gene of any nucleotide sequence from any biological source claim 1) or any plant in a method of identifying a candidate herbicidal compound.

The standard for meeting the enablement requirement is whether one of skill in the art can make the invention without undue experimentation. The amount of experimentation to make the claimed invention is enormous and undue. Such experimentation entails performing an assay using all known and yet to be discovered FHT molecules having different sequences, fragments

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and variants in a method of identifying a candidate herbicidal compound. Thus, using any FHT from any specific biological source (as in claim 1) or from any plant (claim 2, 5-9, 12, 13, 16 and 17) in the method of identifying a candidate herbicidal compound is well outside the realm of routine experimentation and specification regarding the specific of FHT and variant and fragments thereof.

The Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific nucleotide sequence of the amino acid sequences of the FHT with at least 80 or 85% sequence identity with any plant FHT or the sequence with at least ten consecutive amino acids of any plant FHT. Without such a guidance, the experimentation left to those skilled in the art is undue.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al

(US 6570064 B1 or WO 99/43825). Allen et al teach the isolation, the recombinant expression and various uses of Flavanone 3-hydroxylase (FHT) from soybean and *Impatiens balsamina*. They teach the use of said FHT in a method of evaluating at least one compound for it's ability to inhibit the activity of a flavanone 3-hydroxylase purified from a recombinant source in view of designing/identifying inhibitors of flavanone 3-hydroxylases that may be useful as herbicides given that the inhibition of these enzymes in plants may lead to inhibition of plant growth (see page 2 line 30 and page 10, column 2 and lines 35-45). Allen et al also characterize FHT from various plants including from *Arabidopsis thaliana* (NCBI GI 3790548 see page 14 example 3) as potential to be used the method of evaluating at least one compound for it's ability to inhibit the activity of a flavanone 3-hydroxylase. Although Allen et al do not teach the specific steps taken by the claims in the instant application, it would have been obvious to one of ordinary skill in the art to use binding assays as in claim 1-4, 6) or use an enzymatic assay (as in claims 8-12) or to examine the RNA or protein levels of a host cell transformed with an FHT in the presence and absence of a candidate FHT inhibitor and evaluate the effect of the compound on plants (as in claims 5 and 7) for use of such compound as a herbicide.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wisman et al (PNAS vol. 95, pp12432-12437, October, 1998. Knock-out mutant from En-1 mutagenized *A. thaliana* population generate phenylpropanoid biosynthesis phenotypes) in view of Pelletier et al. (Analysis of Flavanoid 3-hydroxylase in Arabidopsis seedlings, Plant physiology (1996) 111:339-345 herein referred to as P-1) or Pelletier et al., Disruption of specific flavonoid genes enhances the accumulation of flavonoid enzymes and end-products in *Arabidopsis thaliana*, Plant Molecular Biology 40: 45-54, (1999) herein referred as P-2). Wisman et al teach the generation of 8,000

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Arabidopsis thaliana plant variants by inserting the maize transposable element En-1 in *Arabidopsis thaliana* in view of identifying the function of genes from this organism. One of the insertions that occurred at the TT6 locus knocked out the Flavanone 3-hydroxylase activity. The essential role of the Flavanoid 3-hydroxylase gene for *Arabidopsis* seeding and for protection from UV-damage during early is taught by Pelletier et al. (P-1). Pelletier et al. teach that F3H (FHT) catalyses an early step in flavonoid metabolism, the formation of dihydroflavanons from flavanols, and therefore provides precursors for many classes of flavonoid compounds. Pelletier et al. (P-1) also teach temporal expression of *Arabidopsis thaliana* flavonoid biosynthetic genes including F3H and determined mRNA levels at various time points by RNA blot analysis. Thus probes and detection method of mRNA were used by Pelletier et al. (P-1). Pelletier et al. (P-2) teach how to make and use antibodies directed to various enzymes involved in the flavonoid biosynthetic pathway including flavanone 3-hydroxylase. Given all the above teachings and the need for developing herbicides, it would therefore have been obvious for a skilled artisan to be motivated to identify a compound that interferes or inhibits the activity of flavanone 3-hydroxylase in view of using such compound as a herbicide. In order to identify a compound that interferes or inhibits the activity of flavanone 3-hydroxylase one of skill in the art would therefore have to perform assays drawn to identifying compounds that bind to FHT (claims 1 - 4 and 6), or compounds that interfere with the enzymatic reaction catalysed by FHT (claims 8-12) or on the expression of FHT mRNA using probes such as disclosed by Pelletier et al. (P-1) (claims 13-16) or polypeptide levels using antibodies as disclosed by Pelletier et al. (P-2) (claims 13-15, 17) followed by testing any candidate compound for its effect on the growth of specific types of undesirable plants (claims 5 and 7).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kagnew H. Gebreyesus whose telephone number is 571-272-2937. The examiner can normally be reached on 8:30am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Achutamurthy ponnathapura can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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